Docket No.: PF-0576-1 DIV

Response Under 37 C.F.R. 1.116 - Expedited Procedure
Examining Group 1652

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By: _____ Printed: Jeannie G. Labra

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Hillman et al.

Title:	EXTRA-CELLULAR ADHESIVE PROTEINS		
Serial No.:	09/747,804	Filing Date:	December 22, 2000
Examiner:	Hutson, R.	Group Art Unit:	1652

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REPLY BRIEF

Sir:

This is Appellants' Reply Brief On Appeal (submitted in triplicate) in response to the Examiner's Answer dated September 23, 2003 ("the Examiner's Answer") in the above-identified application.

In the Examiner's Answer the Patent Examiner:

(1) maintained the rejection of claims 1 and 13 under 35 U.S.C. § 112, first paragraph for allegedly lacking written description of the claimed polypeptide variants.

I. WRITTEN DESCRIPTION REJECTION

Nowhere in the Examiner's Answer does the Examiner offer any evidence that one of ordinary skill in the art would not have understood, from the disclosure in the specification, along with "[w]hat is conventional or well known to one of ordinary skill in the art," that Appellants were in possession of the claimed polypeptide variants. The Examiner instead states that "[t]he specification...only provides the representative species of SEQ ID NO:1, encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship for the disclosed species." (Examiner's Answer, page 3).

The Examiner's position is contrary to the Patent and Trademark Office's own written description guidelines ("Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1", published January 5, 2001), which provide that:

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. **What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.** (emphasis added)

Here, there simply is no requirement that the claims recite the exact amino acid sequences of particular polypeptide variants because the claims already provide sufficient structural definition of the claimed subject matter. That is, the claimed polypeptide variants are defined in terms of SEQ ID NO:1. Because the claimed polypeptide variants are defined in terms of SEQ ID NO:1, the precise chemical structure of every polypeptide variant within the scope of the claims can be discerned. The Examiner's position is nothing more than a misguided attempt to require Appellants to unduly limit the scope of their claimed invention.

All of the claimed polypeptides are structurally related because they are all defined in terms of the structure of SEQ ID NO:1, an amino acid sequence which is explicitly disclosed in the application

(see, e.g., the Sequence Listing and Figures 1A and 1B). Appellants point to the recitation of "a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1" in claim 1 as an example in which the recited polypeptides have been claimed by their structure.

In the Appeal Brief filed July 1, 2003, Appellants asserted that Brenner teaches that "30% identity is a reliable threshold for establishing evolutionary homology between two sequences aligned over at least 150 residues" and that "≥40% identity over at least 70 residues is reliable in signifying homology between proteins" (Appeal Brief, page 9.) Appellants stated that "naturally occurring molecules may exist which could be characterized as human prostate carcinoma tumor antigen-1 or proteins belonging to the galectin class of proteins and which have as little as 30% identity over at least 150 residues to SEQ ID NO:1" and that variants (having at least 90% amino acid identity to SEQ ID NO:1) show variation that "is far less than that of all potential galectin proteins related to SEQ ID NO:1, i.e., those galectin proteins having as little as 30% identity over at least 150 residues to SEQ ID NO:1." (Appeal Brief, page 10.) Thus, the claimed genus is of relatively narrow scope.

The Examiner, however, dismisses Appellants' arguments, alleging that "[w]hile it may be that an evolutionary relationship may exist between two molecules with as little as 30% identity over a region of at least 150 residues, this does not in any way reflect on the description of those naturally occurring molecules or whether a single species is representative of the claimed naturally occurring molecules." (Examiner's Answer, page 8.) Appellants respectfully submit that the Brenner reference was submitted in response to the Examiner's assertion that "[t]he genus of proteins that are claimed is a large variable genus with potentiality of comprising many functionally unrelated proteins." (Office Action of June 4, 2002 at page 7.) The question of whether the written description of the claimed polypeptides is sufficient under the requirements of 35 U.S.C. § 112, first paragraph has been addressed in paragraphs 2-4 above and paragraphs 7-10 below.

On page 7 of the Examiner's Answer, the patent Examiner alleges that "[w]hile one of skill in the art, provided the sequence of SEQ ID NO:1, may be able to recognize variants of SEQ ID NO:1 with an amino acid sequence sharing greater than 90% identity, one cannot recognize which of these variants occurs naturally and is thus encompassed by the genus of claim 1 part b)."

Appellants submit that the term "naturally occurring" is a well-known term in the art which Appellants intended to be used in such context. As such, no further definition of the term is necessary (MPEP 2163 IIA3(a)):

> What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

One of ordinary skill in the art would recognize that "***a naturally occurring amino acid sequence***" as recited in claim 1 b) is one which occurs in nature. Through the process of natural selection, nature will have determined the appropriate amino acid sequences. Given the information provided by SEQ ID NO:1 (the amino acid sequence of EXADH) and SEQ ID NO:3 (the polynucleotide sequence encoding EXADH), one of skill in the art would be able to routinely obtain "a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1, said naturally occurring amino acid sequence ***having extracellular adhesion activity***." [Emphasis added.] The amino acid sequence of SEQ ID NO:1 is provided in the Sequence Listing and in Figures 1A and 1B. The identification of relevant polynucleotides could be performed, for example, by hybridization and/or PCR techniques that were well-known to those skilled in the art at the time the subject application was filed and/or described throughout the Specification of the instant application. (See Specification, *e.g.*, at p. 31, line 26 to p. 32, line 1; and Example VI at p. 40). The specification also describes expression vectors for the production of the claimed polypeptide variants and the construction of fusion proteins (pp. 18-22 and Example IX at pp. 41-42). An assay for extracellular adhesion activity is provided in the Specification, for example, in Example X at page 42. Additional assays for determining extracellular adhesion function in a cell are provided in the Specification, for example, in Example XI at pages 42-43. Given this information, one of skill in the art would be able to routinely obtain a polynucleotide encoding "a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1,

said naturally occurring amino acid sequence having extracellular adhesion activity." Accordingly, the Specification provides an adequate written description of the recited polypeptide sequences.

On page 8 of the Examiner's Answer, the Examiner alleges that Appellants arguments based on decisions rendered in *University of California v. Eli Lilly* and *Fiers v. Revel*, are not persuasive because "given the lack of representative species as encompassed by the claims, appellants have failed to sufficiently describe the claimed invention." Appellants respectfully point out that in the cases of *University of California v. Eli Lilly* and *Fiers v. Revel*, the court found that functional language was insufficient to provide an adequate written description. However, these cases do not stand for the proposition that the patent applicant must provide more than what is required by law in order to meet the written description requirement of 35 U.S.C. § 112, first paragraph. By the Patent Office's own guidelines, the written description requirement can be satisfied by "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics" (P.T.O. Guidelines, *supra*; emphasis added). Thus, "complete or partial structure," such as the structural definition of the claimed polypeptides based on at least 90% sequence identity to SEQ ID NO:1, is enough to provide an adequate written description of the claimed invention.

On page 9 of the Examiner's Answer, the Examiner avers that "[t]o fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these." Appellants respectfully submit that the Examiner has, contrary to law, elevated his own interpretation of *University of California v. Eli Lilly and Co.*, to the level of an absolute requirement for written description. Rather than requiring that any additional guidelines for written description be met, the Examiner first should have looked to the USPTO's own written description guidelines, cited above at page 2.

Appellants reiterate that there simply is no requirement that the claims recite the exact amino

acid sequences of particular polypeptide variants because the claims already provide sufficient structural definition of the claimed subject matter. That is, the claimed polypeptide variants are defined in terms of SEQ ID NO:1. Because the claimed polypeptide variants are defined in terms of SEQ ID NO:1, the precise chemical structure of every polypeptide variant within the scope of the claims can be discerned. The Examiner's position is nothing more than a misguided attempt to require Appellants to unduly limit the scope of their claimed invention.

For at least the above reasons, reversal of the written description rejection is requested.

II. CONCLUSION

For all the foregoing reasons and the reasons stated in Appellants' Brief on Appeal, it is submitted that the Examiner's rejections of the claims on appeal should be reversed.

If the USPTO determines that any additional fees are due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

This brief is enclosed in triplicate

Respectfully submitted,

INCYTE CORPORATION

Date: 18 November 2003

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APPENDIX - CLAIMS ON APPEAL

1. An isolated polypeptide selected from the group consisting of:

a) a polypeptide comprising the amino acid sequence of SEQ ID NO:1, and

b) a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1, said naturally occurring amino acid sequence having extracellular adhesion activity.

13. A composition comprising a polypeptide of claim 1 and an excipient.